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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,645	09/22/2005	Nikolay Sergeevich Sapronov	36677.14	9402

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HAYNES AND BOONE, LLP
901 MAIN STREET, SUITE 3100
DALLAS, TX 75202

EXAMINER	
CHENG, KAREN	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,645	SAPRONOV ET AL.	
	Examiner	Art Unit	
	Karen Cheng	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27,30,35,38 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/07/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-44 are currently pending in the instant application.

Priority

The application is a 371 of International Application No. PCT/AU03/00972, filed on 7/31/2003, which claims the benefit of foreign priority under 35 U.S.C. 119, to Russian Application No. 2002120366, filed on 08/01/2002. Acknowledgment is made of applicant's claim for foreign priority based on an application on 08/01/2002. It is noted, however, that applicant has not provided an English translation of the document as required by 35 U.S.C. 119(b).

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 12/07/06 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because a brief explanation or description does not appear in the specification. See for example, figures 3 and 5. No mention of these figures can be found in the specification. Additionally figure 6 fails to adequately describe what is being compared in the graphs as described in the specification. Figure 6 shows three graphs but the graphs are not labeled so it is unclear what is being shown. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: The applicant's middle name is misspelled as Konstantinovna rather than Konstantinovan.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The scope of claims 6 and 30 is confusing and the examiner has ascertained that there are multiple ways of interpreting these claims:

1) The claim(s) contain a compound in which R^1 or R^2 is a sulphonamide group, and this sulphonamide group is then substituted with an alkyl chain of 1 to 6 carbons OR

2) The claim(s) contain a compound in which R^1 or R^2 is an alkyl chain of 1 to 6 carbon atoms that is then substituted with a sulphonamide OR

3) The claim(s) contain a compound in which R^1 or R^2 is an alkyl chain of 1 to 6 carbon atoms that is then substituted with a sulphonamide and the sulphonamide can than be further substituted with an alkyl chain of 1 to 6 carbon atoms.

Claims 6 and 30 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Further Claims 6 and 30 recites the limitation "a substituted sulphonamide". There is insufficient antecedent basis for this limitation in the claim as Claim 6 is dependent on Claim 4, which is dependent on Claim 3, and there is no mention of a sulphonamide substituent in this claim. Claim 30 is dependent on Claim 27, which does not mention a sulphonamide substituent.

Claims 3, 11, 26-27, 35, and 38 are rejected for containing language that appears to be a literal translation into English from a foreign document and contain idiomatic errors or unfamiliar terminology. It is suggested that gentisate be replaced with dihydroxybenzoate in the claims.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 43 recites the broad recitation "a method of promoting tissue repair, promoting wound healing" which is similar to claim 1, and claim 43 also recites "or reducing inflammation" which is the narrower statement of the range/limitation, which is similar to claim 2. Claim 2 is dependent on claim 1, and thus is regarded as a limitation (i.e. a narrower statement) of Claim 1. Since claim 43 contains the language of both claims 1 and 2, it is considered indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoting tissue repair and being enabling for wound healing that reduces scar formation, does not reasonably provide enablement for wound healing that prevents scar formation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is directed to a method of promoting tissue repair or wound healing that reduces or prevents scar formation in a subject suffering from a condition such as traumatic wounds, surgical wounds, burns, etc compromising

administering an effective amount of 1,3-dialkyl-4,5-bis(optionally N-substituted carbamoyl) imidazolium salt.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds prevent scar formation). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that that contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any preventive regimen on its fact.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The burden of enabling one skilled in the art to prevent scar formation would be much greater than that of enabling the reduction of scar formation. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing scar formation.

"To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Webster's II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compositions can be administered to order to have the "prevention" effect.

There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with formation of scar in general. Moreover, as seen in the prior art, with the exception of very minor lesions, every wound results in some degree of scarring. When wound healing occurs, it occurs through the formation of a predominantly fibrous tissue. If the injury sections or destroys the papillary layer of the stratum corneum, a scar will always be formed as part of the healing process. Although some scars may be less conspicuous than others, scar formation, such as widened scars, occurs with no predilection to sex or ethnicity. No inheritance pattern is associated with the risk for scar widening. Since abnormal scar formation is unique to humans, animal model research has not contributed much to our understanding. Therefore, results from animal models cannot be said to translate to success in humans (Wilhelmi *et al)*. Since applicants "preventive" assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits.

Applicants have not provided any competent evidence or disclosed test results that are highly predictive for the pharmaceutical use of preventing scar formation. Although applicants provide results in the specification detailing the healing of wounds, there is nothing on record to show that no scarring is present. Hence, one of skill in the art is unable to fully predict possible preventive results from the administration of the claimed compound due to the absence of convincing evidence.

The amount of direction or guidance present and the presence or absence of working examples

The specification gives example of wound healing and tissue repair in rats and human subjects. However, no indication of the prevention of scar tissue is given.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include prevention of scar formation but the specification only provides evidence for the reduction of scar formation using the claimed compound.

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain the effectiveness of the compounds in the prevention of scar formation. Factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. Scar formation is a complex process that cannot be prevented since skin heals through the formation of predominantly fibrous tissue, which is scar tissue. It is a natural part of wound healing. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of preventing scar formation, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claim.

In consideration of the Wand factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual

data to the contrary, the amount and level of experimentation needed is undue. Therefore, claims 1-26 are rejected under 35 U.S.C. § 112, 1st paragraph.

Conclusion

A search was made of the prior art, and the closest art was found in Farmakologiya i Toksikologiya (Moscow) (1984), 47(2), p. 23-8. whereby a similar compound, 4,5-di(methylcarbamoyl)-1-ethyl-imidazole, otherwise known as ethimizol, that does not have an alkyl group on the N_3 atom of the imidazole ring is disclosed to be useful in treatment of lesions resulting from gastric ulcers. Although ethimizol has been disclosed in treating ulcerative lesion of the gastric mucosa, there is no suggestion of the use of the di-N-alkylated imidazolium salts in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REBECCA ANDERSON
PATENT EXAMINER

Karen Cheng
Patent Examiner, AU 1626

Joseph McKane
Supervisory Patent Examiner, AU 1626